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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,040	03/01/2002	Joseph C. Cauthen	08442.0002-04	8078

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FAEGRE & BENSON LLP
PATENT DOCKETING - INTELLECTUAL PROPERTY
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MINNEAPOLIS, MN 55402-3901

EXAMINER

GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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03/16/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/085,040	Applicant(s) CAUTHEN, JOSEPH C.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 102-107, 109-112, 114-133, 137-139, 141, 142, 183 and 184 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102-107, 109-112, 114-133, 137-139, 141, 142, 183 and 184 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/12/07, 1/18/08, 6/16/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicant's amendment filed on 9/6/2007 has been entered. Currently, claims 102-107, 109-112, 114-133, 137-139, 141, 142, and 183-184 are pending for consideration.

Response to Arguments

1. Applicant's arguments filed 9/6/2007 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

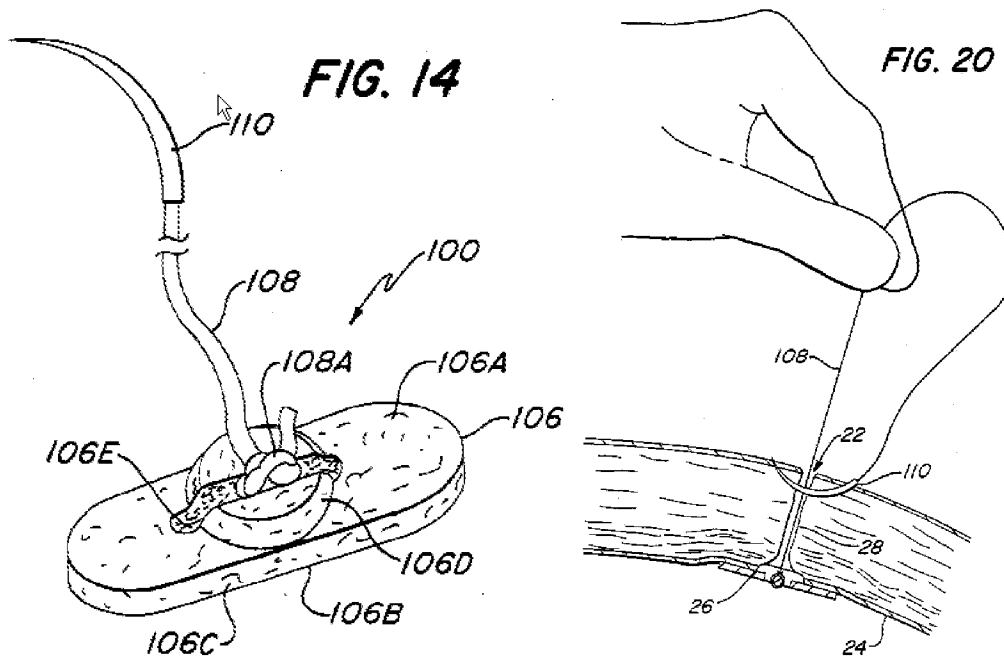
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 102-108, 112, 114-118, 120-121, 123-127, 130-131, 133, 137-139, and 141-142 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash (U.S. Pat. No.: 5,545,178).

Nash discloses a closure device (see fig 14, reproduced below) that is capable of tissue ingrowth (fig. 28 and related description) including a main body portion (106D) having proximal and distal ends (top and bottom surfaces, respectively), the main body 106D does not have any extension at its proximal (top) end. Nash further discloses an extension (on either side of 106D) having an axis projecting along a reference plane that is lateral from the main body. The

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extension is flexible and can deflect from its reference plane with sufficient force, however note that the claim merely requires that the axis flexibly deflect, thus this limitation does not actually require a flexible device. The device further comprises a fixation element 108 that passes through tissue surrounding the aperture (fig. 20).



Claim 103, see fig. 14 and 20.

Claim 104, see column 13, lines 50+.

Claim 105, see figure 21, element 108B.

Claim 106, see figure 20.

Claim 107, see figure 14, 20.

Claim 112 (see fig. 14, 20).

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Claims 114-118, 120-121, 123-127,130,131 see fig. 6, 14 and columns 4 lines 20+ and col. 13 lines 25-33, noting that the collagenous material of fig. 6 can be part of the device.

Claim 133, col. 11 line 32- col. 21 line 27.

Claims 137-139, see figure 14 of Nash.

Claims 141-142, see knot 108A, fig. 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 109-111,119, 122,128-129, 132, and 183-184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash and further in view of Gilson [5904703], Bao et al. (USPN 6,224,630) and Carr, Jr. et al (5733337).

Nash discloses, generally, that the device is fabricated from collagen foam or PLA/PGA that is resorbable. Gilson teaches that the occluder device (60) is made from a compressible, porous polymeric foam in column 4, lines 30-31 and 55-58. Bao et al. teaches the occluder device also being made from a compressible, porous polymeric foam in column 3, lines 15-19 and column 5, lines 36-42. The foam can be made from bioresorbable collagen fibers and interwoven biocompatible polymeric fibrils that by nature provide a membrane,

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fabric or sheet or ePTFE (Claims 57,58,64-66,70-76; column 5, lines 56-57).

These materials can be made sufficiently porous to permit tissue ingrowth into the material from surrounding tissue of the implant site. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Gilson and/or Bao et al. to make the polymeric material of the device 100 of Nash from the materials required by claims sufficient porosity to permit tissue ingrowth into the material from surrounding tissue of the implant site. When the device Nash, as modified by Gilson and/or Bao et al., is used to treat an intervertebral disc wall, the material of the device will facilitate regeneration of disc tissue by promoting tissue ingrowth from the surrounding annulus. See column 14, lines 14+ of Bao et al for teachings of equivalent fastening elements.

Carr, Jr. et al. teach a tissue repair fabric that can be implanted to repair, augment or replace structures including intervertebral discs (column 4, lines 43-53). The tissue repair fabric comprises collagenous tissue obtained from autograft, allograft or xenograft fascia lata or pericardium, in order for the fabric to undergo controlled biodegradation accompanied by adequate living cell replacement, or neo-tissue formation, such that the original implanted prosthesis is remodeled by the host's cells before it is degraded by host enzymes when implanted into the host. See column 2, lines 13-24, 36-38 and 65-66. Carr et al. also teaches the additional limitation of the tissue repair fabric including growth factors (claims 62 and 63; column 8, lines 13-15) in order to promote

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vascularization. The graft fascia lata is considered to be a patch of human muscle fascia.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774